DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

NDA 20-987/S-004

Wyeth-Ayerst Laboratories
Attention: Ms. Mary Alice Dankulich
Associate Director, Worldwide Regulatory Affairs
P.O. Box 8299
Philadelphia, PA 19101-8299

Dear Ms. Dankulich:

Please refer to your supplemental new drug application dated September 14, 2000, received September 15, 2000, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Protonix®(pantoprazole sodium) Delayed-Release Tablets, 40 mg.

We acknowledge receipt of your submission dated March 30, 2001. Your submission of March 30, 2001 constituted a complete response to our March 14, 2001 action letter.

This supplemental new drug application provides for deletion of text pertaining to dose adjustment for patients with renal or hepatic impairment, or elderly patients in the following package insert labeling sections:

- CLINICAL PHARMACOLOGY/Special Populations/Hepatic Impairment
- PRECAUTIONS/General
- DOSAGE AND ADMINISTRATION/Treatment of Erosive Esophagitis

Additionally, comparative omeprazole PK/PD data have been deleted from the package insert labeling as requested in the Agency's February 9, 2001 letter.

We have completed the review of this supplemental new drug application, as amended, and have concluded that adequate information has been presented to demonstrate that the drug is safe and effective for use as recommended in the final printed labeling submitted on March 30, 2001. Accordingly, the supplemental new drug application is approved effective on the date of this letter.

If a letter communicating important information about this drug product (i.e., a "Dear Health Care Professional" letter) is issued to physicians and others responsible for patient care, we request that you submit a copy of the letter to this NDA and a copy to the following address:

MEDWATCH, HF-2
FDA
5600 Fishers Lane
Rockville, MD 20857

We remind you that you must comply with the requirements for an approved NDA set forth under

21 CFR 314.80 and 314.81.

If you have any questions, call Cheryl Perry, Regulatory Health Project Manager, at (301) 827-7475.

Sincerely,

{See appended electronic signature page}

Lilia Talarico, M.D.
Director
Division of Gastrointestinal and Coagulation Drug Products
Office of Drug Evaluation III
Center for Drug Evaluation and Research